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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/026,882 | 02/19/1998 | MICHAEL G. ROSENBLUM | D5442C/CIP | 2401 |

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EXAMINER

HUFF, SHEELA JITENDRA

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1642

DATE MAILED: 07/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/026,882

Applicant(s)

ROSENBLUM, MICHAEL G.

Examiner

Sheela J Huff

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 1-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/4/02 has been entered.

Claims 1-17 are pending.

Claims 1-7 and 16-17 are withdrawn from consideration as being drawn to a non-elected invention.

Claims 8-15 are pending.

Response to Arguments

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 8-15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Tanimoto et al, Leukemia, vol. 3 p. 339 (1989) or Scheinberg et al, Leukemia, vol. 3 p. 440 (1989) in view of Thorpe et al, Immunological Reviews vol. 62 p. 119 (1982) and Andrews et al Blood, vol. 62 p. 124 (1983) and Rosenblum et al US 5631348 (filed 8/14/90). The reasons for this rejection are of record in paper no. 7, mailed 12/27/99.

Applicant argues each reference individually. The arguments presented against Tanimoto, Scheinberg, Andrews and Rosenblum have already been acknowledged in the rejection. With respect to Thorpe, applicant cites several portions of page 120. Applicant has mischaracterized this section. The paragraph in question is an overview of the reference. Thus, overview indicates that two different methods for conjugation will be discussed. The first one is discussed at lines 6-13. On page 120, lines 10-12, applicant neglected to include the first part of the sentence which states "[p]art of the present review will concern the preparation and cytotoxic properties of such conjugates, particularly the way in which the different types of linkage used in constructing the conjugate influence its biological properties". Thus, the entire reference discloses different conjugation methods and indicates which linker is better for what. Applicant has also mischaracterized lines 14-17 of page 120. This section refers to the second method, which is directed to linking the isolated A-chain from a toxin to the antibody and

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it is these conjugates whose cytotoxic potency is variable and unpredictable. It is noted that applicant's claims are not directed to conjugates concerning the A-chain of gelonin.

Applicant argues that the effectiveness of an immunoconjugate depends on a number of factors: type of toxin, method of conjugation, the mab, the nature of the target cells and mode of administration. Thorpe shows a conjugate made using gelonin, and this conjugate is effective in cell killing. Thus, one of ordinary skill in art all ready knows that the toxin can be successfully conjugated and what method to use. The mab has already been shown to specifically bind to target cells and both primary references clearly suggest the use of the mab as a carrier for toxins. Furthermore, applicant is directed to Scheinberg US 5730982, which shows that a conjugate containing M195 is successfully administered in vivo, thus, applicant's arguments with respect to mode of administration and nature of cell has been addressed.

Applicant further provides a declaration to show unexpected results. A proper showing of unexpected results is a direct comparison between the closest prior art and applicant's invention. Applicant did not do this.

Claims 8-15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Scheinberg US 5730982 (filed 12/14/89) in view of Thorpe et al, Immunological Reviews vol. 62 p. 119 (1982) and Andrews et al Blood, vol. 62 p. 124 (1983) and Rosenblum et al US 5631348 (filed 8/14/90). The reasons for this rejection are of record in paper no. 7, mailed 12/27/99.

Applicant's arguments have been addressed above.

Conclusion

No claim is allowed

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J Huff whose telephone number is 703-305-7866. The examiner can normally be reached on M,Th 5:30 am-2:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Sheela J Huff
Primary Examiner
Art Unit 1642

sjh
July 2, 2002